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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/811,129

03/29/2004

David G. Whitten

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EXAMINER

COUNTS, GARY W

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/811,129

Applicant(s)

WHITTEN ET AL.

Examiner

Gary W. Counts

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07/19/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>07/20/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment filed on 07/19/06 and the RCE filed 06/21/06 has been entered.

Claim Rejections - 35 USC § 112

2. Claims 40-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To the extent that the claimed compound and J-aggregate fluorescent polymer are not described in the instant disclosure, claims 40-58 are rejected under 35 U.S.C. 112 first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

The recitation "amplified superquenching of the J-aggregate fluorescent polymer when associated therewith" as recited in amended claim 40. Although the specification

Art Unit: 1641

describes that polymer-QTL technology has significant amplification in quenching (page 3, lines 3-18) and describes superquenching (page 13, lines 18-22 & page 14, lines 1-21), the specification fails to define or provide any disclosure to support such claim recitation.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 40-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40, line 15 the recitation "amplified superquenching" is vague and indefinite. It is unclear what is considered to be "superquenching". The specification on pages 13 and 14 mentions "superquenching". However, the specification does not provide a definition for the term and it is unclear what is considered to be "amplified superquenching".

Claim 40 is vague and indefinite because it is unclear how the J-aggregate fluorescent polymer and the property-altering element are "associated". Are they bound together or in close proximity to one another?

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

Art Unit: 1641

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 40, 42 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al (US 6,979,543) or Chen et al (US 6,589,731).

Chen et al ('543 and '731) disclose a kit for the detection of biological agents (col 2). Chen et al disclose that the kit can comprise a fluorescent polymer, a recognition element bound to a property-altering element (col 2 and Fig. 2). Chen et al disclose that a tether links the recognition element to the property-altering element. Chen et al disclose that the fluorescent polymer is quenched by the property-altering element when associated. Chen et al disclose that the recognition element can be antibodies, antigens and chemical ligands (col 5). Chen et al also disclose that the property-altering element can be viologen (col 6).

With respect to the recitation "J-aggregate". The specification does not define the term J-aggregate. Since MPS-PPV becomes an aggregate in the presence of divalent cations (col 9), which is a J shape (see Figure 2), in a broad and reasonable interpretation, MPS-PPV is a J-aggregate as recited.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1641

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 40, 42 and 43. rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (PNAS, 1999, Vol 96, No. 22, 12287-12292) in view of Boguslaski (US 5,420,016).

Chen et al disclose a compound comprising biotin (recognition element) linked by a tether to methyl viologen (property-altering element) (Fig. 2 and page 12290). Chen et al disclose that the property-altering element associates with MPS-PPV (fluorescent polymer). Chen et al disclose that the polymer can be affixed to a support (p. 12291)

With respect to the recitation "J-aggregate". The specification does not define the term J-aggregate. Since MPS-PPV becomes an aggregate in the presence of divalent cations (page 12289, right column), which is a J shape (see Figure 2A), in a broad and reasonable interpretation, MPS-PPV is a J-aggregate as recited.

Chen et al differ from the instant invention in failing to teach the components packaged into a kit.

Boguslaski et al disclose assembling various components into a kit and also discloses that by assembling these components into kits makes it more convenient and facile for the test operator.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to package the components as taught by Chen et al into a kit such as taught by Boguslaski et al because Boguslaski et al teaches that assembling components into kits makes it more convenient and facile for the test operator.

It is noted that Duncan W. McBranch and David G. Whitten are named as coauthors of Chen et al entitled "highly sensitive Biological and Chemical Sensors Based on Reversible Fluorescence Quenching in a Conjugated Polymer" (PNAS, 96, 22, 12287-12292 (1999)) and that Duncan W. McBranch and David G. Whitten are also named as inventors of the current application. However, Liaohai Chen, Hsing-Lin Wang, Roger Helgeson and Fred Wudl are also listed as authors and therefore the publication is considered to be by others. Also, it is noted that the current Application also lists Roberts Jones and Troy S. Bergstedt as inventors and even if Liaohai Chen, Hsing-Lin Wang, Roger Helgeson and Fred Wudl were removed from the paper. The current

Art Unit: 1641

application and publication would not match up because of the listing of Jones and Bergstedt and therefore would still be considered by others.

It is recommended to submit declarations (such as done in application 09/850,074) to remove the Chen et al publication entitled "highly sensitive Biological and Chemical Sensors Based on Reversible Fluorescence Quenching in a Conjugated Polymer" (PNAS, 96, 22, 12287-12292 (1999)).

Response to Arguments

11. Applicant's arguments with respect to claims 40-58 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

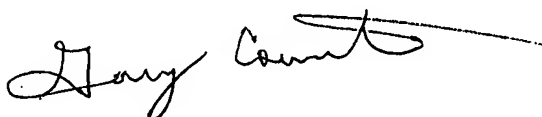
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Gary Counts
Examiner
Art Unit 1641
August 14, 2006



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